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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,543	10/30/2003	Jianping Cai	21454	7592
151	7590	10/11/2005	EXAMINER	
HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/697,543	Applicant(s) CAI ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 41-43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-29 and 40 is/are allowed.
- 6) ☒ Claim(s) 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

100

DETAILED ACTION

1. This action is in response to an application filed on 10/30/03. There are forty-three claims pending and forty under consideration. Claims 1-30 are compound claims. Claim 40 is a composition claim. Claims 31-36 are method of making claims. This is the first action on the merits. The application concerns some pyrimido[4,5-d]pyrimidin-2-one compounds, compositions, and synthesis thereof.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-40, drawn to compounds and compositions of formula I, classified in class 544, subclass 256, among others.
- II. Claims 41-43, drawn to therapeutic uses of those compounds, classified in class 514, subclass 262.1.

3. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case Applicants admit their compounds have at least three different general classes of uses. Also there are many different drugs that can be used to treat a variety of CNS diseases. For example depression may be treated with amitriptyline. Thus, both prongs of the test are met. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

5. During a telephone conversation with Patricia Rocha-Tramaloni on 9/29/05 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-40. Applicant in replying to this Office action must make

affirmation of this election. Claims 41-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

7. Claims 9, 14, 18, 21, 27, and 29 are objected to because of the following informalities: once in claim 9, once in claim 14, twice in claim 18, five times in claim 21, twice in claim 27, and seven times in claim 29, Applicants have the following character string in a chemical name, "lambda*6*". Was "-6" intended? Appropriate correction is required.

8. Claims 37 and 38 are objected to because of the following informalities: the two words "comprising converting" have been transformed into a single word. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the last line of the claim, Applicants have the limitation "an optionally protected NH₂ group". With what and against what is the amino group to be protected? In paragraph [0082], page 29 beyond the statement that such groups are "known in the art", there is no direction as to what groups are intended. Some amino protecting groups, like t-BOC are stable to base but cleaved by acid. Some amine protecting groups, like Cbz are stable to both acid and base. Some amino protecting groups, like the Fmoc group are stable to acid but removed by base. Unless the skilled chemist knows against what conditions the amino group is to be protected, then there is no way she can understand the limitations of this claim.

10. Claims 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In both the second line and in the line immediately above formula (III) of claim 31, Applicants' have the limitation "general formula". The word "general" implies more than one formula is being claims. The Examiner suggests removing the word "general".

11. Claims 31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the second line above formula (III) in claim 31, Applicants have the limitation, "L signifies a leaving group". In the sentence bridging pages 18 to 19 of the specification, Applicants have an open definition of the term. In the last three lines on page 19, there is a different definition of the concept of "leaving group". Which one is intended? In addition to the radicals listed in these two lists, what else is being claimed? As explained by A D McNaught & A Wilkinson, in "IUPAC Compendium of Chemical Terminology, 2nd Ed", "[t]he term [leaving group] has meaning only in relation to a specified reaction." This means that a universal list of such groups is not possible and the leaving groups in molecule (II) must differ from the leaving groups in molecule (V).

12. Claim 33 recites the limitation "deprotecting a protected hydroxy or protected amino group" in lines 1 and 2. There is no antecedent basis for this limitation in the parent claim 31, which does not mention any protecting groups.

13. Claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the line immediately below formula

II, Applicants have the limitation "or a protected amine". According to Hawley's an amine is "[a] class of organic compounds of nitrogen that may be considered as derived from ammonia (NH_3) by replacing one or more of the hydrogen atoms with alkyl groups. The amine is primary, secondary, or tertiary depending on whether one, two, or three of the hydrogen atoms are replaced." Examples of this would be methyl, dimethyl, and trimethyl amine. None of these are suitable for reacting with II to give (IV). Applicants presumably mean a protected version of ammonia like phthalimide. Since a careful reading of Hawley's definition would imply that ammonia itself is not an amine, the Examiner suggests replacing "amine" by "ammonia". Since we know what reaction and reaction conditions are intended, there is no problem with the concept of "protected ammonia".

14. Claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the line immediately below formula II, Applicants have the limitation "cleaving the protecting group L". This is indefinite for two reasons. Firstly, L is not a protecting group it is "a leaving group". Secondly, if molecule II is reacted with ammonia, then there is no protecting group to remove. The Examiner suggests "cleaving any optional protecting group from the product".

15. Claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the penultimate line of the claim, Applicants have the limitation "a leaving group". This was discussed above.

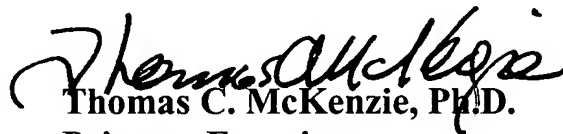
Allowable Subject Matter

16. Claims 1-29 and 40 are allowed. Claims 30-39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

17. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

18. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


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